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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,350	04/18/1997	ALASDAIR R. MACLEAN	117-231	1818

23117 7590 08/15/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/15/2003

58

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
08/776,350Applicant(s)
MacLean et alExaminer
UngarArt Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 27, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires three months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: The new issue raised is drawn to the limitation of "consisting of an HSV-1 genome"

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none

Claim(s) objected to: none

Claim(s) rejected: 43-45, 47, and 51

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).

10. ☐ Other:

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

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1. If the amendment were to be entered, rejection under 35 USC 103 would be maintained for the reasons previously set forth in Paper No.34, Section 5, pages 1-2, Paper No. 31, Section 7, pages 4-6, Paper No. 25, Section 7, pages 6-7, Paper No. 23 Section 7, pages 5-6, Paper No. 21, Section 8, pages 8-10.

Applicant argues that the amended claim does not include a non-functional ribonucleotide reductase gene as required by the combination of the cited art. The argument has been considered but has not been found persuasive because the claim as amended does not exclude mutations other than mutations gamma 34.5. The consisting language is drawn only to the HSV-1 genome and not to a sole mutation of the gamma 34.5 gene. Further, even if the amendment were to be entered, it would still not overcome the rejection because the combined art does not require a non-functional ribonucleotide reductase gene for the reasons of record. In particular the successful intracranial treatment of glioma was accomplished with an HSV-1 with only a deletion in the gamma 34.5 gene, R3616, which did not have a deletion in the ribonucleotide reductase gene. As previously set forth the argument is drawn only to the cited US Patent without clearly addressing the combined teachings wherein it was known in the art that melanoma metastasizes to the brain and that HSV-1 infects metastatic melanoma and that HSV-1 mutant 1716 was known. One would have expected to successfully substitute the mutant 1716 for the construct of the US Patent because R3616 was shown to be effective for the treatment of intracranial tumor. In view of the above, given the references in combination, for the reasons of record the claimed invention is obvious.

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2. If the amendment were to be entered the objection to the introduction of new matter would be maintained.

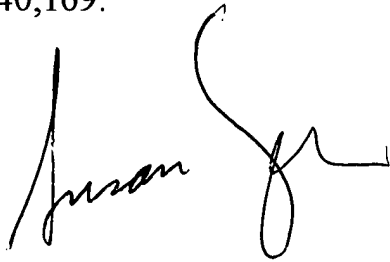
Applicant filed a Declaration Pursuant to MPEP 608.01(p) I.A.2 wherein he declared that WO92/13943 is incorporated in the above-identified application by reference and that the disclosure of US Patent No. 6,040,169 which claims benefit of PCT/GB92/00179 is substantially the same. The amendatory material relating to the material incorporated by reference in the Amendment of January 22, 2001, consists of the same material incorporated by reference in the referencing application. The argument has been considered but has not been found persuasive for the reasons of record. That is that a priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p). The fact that both PCT/GB92/00179 and US Patent No. 6,040,169 disclose information about strain 1716 is not relevant to the instant objection. The case as originally filed did not

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include an incorporation by reference to either PCT/GB92/00179 or US Patent No.
6,040,169.

A handwritten signature in black ink, appearing to read "Susan Ungar". The signature is fluid and cursive, with a large initial "S" and "U".

SUSAN UNGAR, PH.D
PRIMARY EXAMINER